

## § 482.1

482.104 Condition of participation: Additional requirements for kidney transplant centers.

AUTHORITY: 42 U.S.C. 1302, 1395hh, 1395rr, and 1395lll unless otherwise noted.

EFFECTIVE DATE NOTE: At 84 FR 51882, Sept. 30, 2019, part 482 was amended by revising the authority citation, effective Nov. 29, 2019.

SOURCE: 51 FR 22042, June 17, 1986, unless otherwise noted.

### Subpart A—General Provisions

#### § 482.1 Basis and scope.

(a) *Statutory basis.* (1) Section 1861(e) of the Act provides that—

(i) Hospitals participating in Medicare must meet certain specified requirements; and

(ii) The Secretary may impose additional requirements if they are found necessary in the interest of the health and safety of the individuals who are furnished services in hospitals.

(2) Section 1861(f) of the Act provides that an institution participating in Medicare as a psychiatric hospital must meet certain specified requirements imposed on hospitals under section 1861(e), must be primarily engaged in providing, by or under the supervision of a physician, psychiatric services for the diagnosis and treatment of mentally ill persons, must maintain clinical records and other records that the Secretary finds necessary, and must meet staffing requirements that the Secretary finds necessary to carry out an active program of treatment for individuals who are furnished services in the hospital. A distinct part of an institution can participate as a psychiatric hospital if the institution meets the specified 1861(e) requirements and is primarily engaged in providing psychiatric services, and if the distinct part meets the records and staffing requirements that the Secretary finds necessary.

(3) Sections 1861(k) and 1902(a)(30) of the Act provide that hospitals participating in Medicare and Medicaid must have a utilization review plan that meets specified requirements.

(4) Section 1883 of the Act sets forth the requirements for hospitals that provide long term care under an agreement with the Secretary.

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(5) Section 1905(a) of the Act provides that “medical assistance” (Medicaid) payments may be applied to various hospital services. Regulations interpreting those provisions specify that hospitals receiving payment under Medicaid must meet the requirements for participation in Medicare (except in the case of medical supervision of nurse-midwife services. See §§ 440.10 and 440.165 of this chapter.).

(b) *Scope.* Except as provided in subpart A of part 488 of this chapter, the provisions of this part serve as the basis of survey activities for the purpose of determining whether a hospital qualifies for a provider agreement under Medicare and Medicaid.

[51 FR 22042, June 17, 1986, as amended at 60 FR 50442, Sept. 29, 1995]

#### § 482.2 Provision of emergency services by nonparticipating hospitals.

(a) The services of an institution that does not have an agreement to participate in the Medicare program may, nevertheless, be reimbursed under the program if—

(1) The services are emergency services; and

(2) The institution meets the requirements of section 1861(e) (1) through (5) and (7) of the Act. Rules applicable to emergency services furnished by nonparticipating hospitals are set forth in subpart G of part 424 of this chapter.

(b) Section 440.170(e) of this chapter defines emergency hospital services for purposes of Medicaid reimbursement.

[51 FR 22042, June 17, 1986, as amended at 53 FR 6648, Mar. 2, 1988]

### Subpart B—Administration

#### § 482.11 Condition of participation: Compliance with Federal, State and local laws.

(a) The hospital must be in compliance with applicable Federal laws related to the health and safety of patients.

(b) The hospital must be—

(1) Licensed; or

(2) Approved as meeting standards for licensing established by the agency of the State or locality responsible for licensing hospitals.

(c) The hospital must assure that personnel are licensed or meet other

applicable standards that are required by State or local laws.

**§ 482.12 Condition of participation: Governing body.**

There must be an effective governing body that is legally responsible for the conduct of the hospital. If a hospital does not have an organized governing body, the persons legally responsible for the conduct of the hospital must carry out the functions specified in this part that pertain to the governing body.

(a) *Standard: Medical staff.* The governing body must:

(1) Determine, in accordance with State law, which categories of practitioners are eligible candidates for appointment to the medical staff;

(2) Appoint members of the medical staff after considering the recommendations of the existing members of the medical staff;

(3) Assure that the medical staff has bylaws;

(4) Approve medical staff bylaws and other medical staff rules and regulations;

(5) Ensure that the medical staff is accountable to the governing body for the quality of care provided to patients;

(6) Ensure the criteria for selection are individual character, competence, training, experience, and judgment; and

(7) Ensure that under no circumstances is the accordance of staff membership or professional privileges in the hospital dependent solely upon certification, fellowship, or membership in a specialty body or society.

(8) Ensure that, when telemedicine services are furnished to the hospital's patients through an agreement with a distant-site hospital, the agreement is written and that it specifies that it is the responsibility of the governing body of the distant-site hospital to meet the requirements in paragraphs (a)(1) through (a)(7) of this section with regard to the distant-site hospital's physicians and practitioners providing telemedicine services. The governing body of the hospital whose patients are receiving the telemedicine services may, in accordance with § 482.22(a)(3) of this part, grant privileges based on its

medical staff recommendations that rely on information provided by the distant-site hospital.

(9) Ensure that when telemedicine services are furnished to the hospital's patients through an agreement with a distant-site telemedicine entity, the written agreement specifies that the distant-site telemedicine entity is a contractor of services to the hospital and as such, in accordance with § 482.12(e), furnishes the contracted services in a manner that permits the hospital to comply with all applicable conditions of participation for the contracted services, including, but not limited to, the requirements in paragraphs (a)(1) through (a)(7) of this section with regard to the distant-site telemedicine entity's physicians and practitioners providing telemedicine services. The governing body of the hospital whose patients are receiving the telemedicine services may, in accordance with § 482.22(a)(4) of this part, grant privileges to physicians and practitioners employed by the distant-site telemedicine entity based on such hospital's medical staff recommendations; such staff recommendations may rely on information provided by the distant-site telemedicine entity.

(10) Consult directly with the individual assigned the responsibility for the organization and conduct of the hospital's medical staff, or his or her designee. At a minimum, this direct consultation must occur periodically throughout the fiscal or calendar year and include discussion of matters related to the quality of medical care provided to patients of the hospital. For a multi-hospital system using a single governing body, the single multi-hospital system governing body must consult directly with the individual responsible for the organized medical staff (or his or her designee) of each hospital within its system in addition to the other requirements of this paragraph (a).

(b) *Standard: Chief executive officer.* The governing body must appoint a chief executive officer who is responsible for managing the hospital.

(c) *Standard: Care of patients.* In accordance with hospital policy, the governing body must ensure that the following requirements are met:

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(1) Every Medicare patient is under the care of:

(i) A doctor of medicine or osteopathy (This provision is not to be construed to limit the authority of a doctor of medicine or osteopathy to delegate tasks to other qualified health care personnel to the extent recognized under State law or a State's regulatory mechanism.);

(ii) A doctor of dental surgery or dental medicine who is legally authorized to practice dentistry by the State and who is acting within the scope of his or her license;

(iii) A doctor of podiatric medicine, but only with respect to functions which he or she is legally authorized by the State to perform;

(iv) A doctor of optometry who is legally authorized to practice optometry by the State in which he or she practices;

(v) A chiropractor who is licensed by the State or legally authorized to perform the services of a chiropractor, but only with respect to treatment by means of manual manipulation of the spine to correct a subluxation demonstrated by x-ray to exist; and

(vi) A clinical psychologist as defined in § 410.71 of this chapter, but only with respect to clinical psychologist services as defined in § 410.71 of this chapter and only to the extent permitted by State law.

(2) Patients are admitted to the hospital only on the recommendation of a licensed practitioner permitted by the State to admit patients to a hospital. If a Medicare patient is admitted by a practitioner not specified in paragraph (c)(1) of this section, that patient is under the care of a doctor of medicine or osteopathy.

(3) A doctor of medicine or osteopathy is on duty or on call at all times.

(4) A doctor of medicine or osteopathy is responsible for the care of each Medicare patient with respect to any medical or psychiatric problem that—

(i) is present on admission or develops during hospitalization; and

(ii) Is not specifically within the scope of practice of a doctor of dental surgery, dental medicine, podiatric medicine, or optometry; a chiropractor; or clinical psychologist, as that scope is—

(A) Defined by the medical staff;

(B) Permitted by State law; and

(C) Limited, under paragraph (c)(1)(v) of this section, with respect to chiropractors.

(d) *Standard: Institutional plan and budget.* The institution must have an overall institutional plan that meets the following conditions:

(1) The plan must include an annual operating budget that is prepared according to generally accepted accounting principles.

(2) The budget must include all anticipated income and expenses. This provision does not require that the budget identify item by item the components of each anticipated income or expense.

(3) The plan must provide for capital expenditures for at least a 3-year period, including the year in which the operating budget specified in paragraph (d)(2) of this section is applicable.

(4) The plan must include and identify in detail the objective of, and the anticipated sources of financing for, each anticipated capital expenditure in excess of \$600,000 (or a lesser amount that is established, in accordance with section 1122(g)(1) of the Act, by the State in which the hospital is located) that relates to any of the following:

(i) Acquisition of land;

(ii) Improvement of land, buildings, and equipment; or

(iii) The replacement, modernization, and expansion of buildings and equipment.

(5) The plan must be submitted for review to the planning agency designated in accordance with section 1122(b) of the Act, or if an agency is not designated, to the appropriate health planning agency in the State. (See part 100 of this title.) A capital expenditure is not subject to section 1122 review if 75 percent of the health care facility's patients who are expected to use the service for which the capital expenditure is made are individuals enrolled in a health maintenance organization (HMO) or competitive medical plan (CMP) that meets the requirements of section 1876(b) of the Act, and if the Department determines that the capital expenditure is for services and facilities that are needed by the HMO or

CMP in order to operate efficiently and economically and that are not otherwise readily accessible to the HMO or CMP because—

(i) The facilities do not provide common services at the same site;

(ii) The facilities are not available under a contract of reasonable duration;

(iii) Full and equal medical staff privileges in the facilities are not available;

(iv) Arrangements with these facilities are not administratively feasible; or

(v) The purchase of these services is more costly than if the HMO or CMP provided the services directly.

(6) The plan must be reviewed and updated annually.

(7) The plan must be prepared—

(i) Under the direction of the governing body; and

(ii) By a committee consisting of representatives of the governing body, the administrative staff, and the medical staff of the institution.

(e) *Standard: Contracted services.* The governing body must be responsible for services furnished in the hospital whether or not they are furnished under contracts. The governing body must ensure that a contractor of services (including one for shared services and joint ventures) furnishes services that permit the hospital to comply with all applicable conditions of participation and standards for the contracted services.

(1) The governing body must ensure that the services performed under a contract are provided in a safe and effective manner.

(2) The hospital must maintain a list of all contracted services, including the scope and nature of the services provided.

(f) *Standard: Emergency services.* (1) If emergency services are provided at the hospital, the hospital must comply with the requirements of § 482.55.

(2) If emergency services are not provided at the hospital, the governing body must assure that the medical staff has written policies and procedures for appraisal of emergencies, initial treatment, and referral when appropriate.

(3) If emergency services are provided at the hospital but are not provided at one or more off-campus departments of the hospital, the governing body of the hospital must assure that the medical staff has written policies and procedures in effect with respect to the off-campus department(s) for appraisal of emergencies and referral when appropriate.

[51 FR 22042, June 17, 1986; 51 FR 27847, Aug. 4, 1986, as amended at 53 FR 6549, Mar. 1, 1988; 53 FR 18987, May 26, 1988; 56 FR 8852, Mar. 1, 1991; 56 FR 23022, May 20, 1991; 59 FR 46514, Sept. 8, 1994; 63 FR 20130, Apr. 23, 1998; 63 FR 33874, June 22, 1998; 68 FR 53262, Sept. 9, 2003; 76 FR 25562, May 5, 2011; 77 FR 29074, May 16, 2012; 79 FR 27154, May 12, 2014]

#### **§ 482.13 Condition of participation: Patient's rights.**

A hospital must protect and promote each patient's rights.

(a) *Standard: Notice of rights.* (1) A hospital must inform each patient, or when appropriate, the patient's representative (as allowed under State law), of the patient's rights, in advance of furnishing or discontinuing patient care whenever possible.

(2) The hospital must establish a process for prompt resolution of patient grievances and must inform each patient whom to contact to file a grievance. The hospital's governing body must approve and be responsible for the effective operation of the grievance process and must review and resolve grievances, unless it delegates the responsibility in writing to a grievance committee. The grievance process must include a mechanism for timely referral of patient concerns regarding quality of care or premature discharge to the appropriate Utilization and Quality Control Quality Improvement Organization. At a minimum:

(i) The hospital must establish a clearly explained procedure for the submission of a patient's written or verbal grievance to the hospital.

(ii) The grievance process must specify time frames for review of the grievance and the provision of a response.

(iii) In its resolution of the grievance, the hospital must provide the patient with written notice of its decision that contains the name of the hospital contact person, the steps taken on behalf of the patient to investigate the

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grievance, the results of the grievance process, and the date of completion.

(b) *Standard: Exercise of rights.* (1) The patient has the right to participate in the development and implementation of his or her plan of care.

(2) The patient or his or her representative (as allowed under State law) has the right to make informed decisions regarding his or her care. The patient's rights include being informed of his or her health status, being involved in care planning and treatment, and being able to request or refuse treatment. This right must not be construed as a mechanism to demand the provision of treatment or services deemed medically unnecessary or inappropriate.

(3) The patient has the right to formulate advance directives and to have hospital staff and practitioners who provide care in the hospital comply with these directives, in accordance with § 489.100 of this part (Definition), § 489.102 of this part (Requirements for providers), and § 489.104 of this part (Effective dates).

(4) The patient has the right to have a family member or representative of his or her choice and his or her own physician notified promptly of his or her admission to the hospital.

(c) *Standard: Privacy and safety.* (1) The patient has the right to personal privacy.

(2) The patient has the right to receive care in a safe setting.

(3) The patient has the right to be free from all forms of abuse or harassment.

(d) *Standard: Confidentiality of patient records.* (1) The patient has the right to the confidentiality of his or her clinical records.

(2) The patient has the right to access information contained in his or her clinical records within a reasonable time frame. The hospital must not frustrate the legitimate efforts of individuals to gain access to their own medical records and must actively seek to meet these requests as quickly as its record keeping system permits.

(e) *Standard: Restraint or seclusion.* All patients have the right to be free from physical or mental abuse, and corporal punishment. All patients have the right to be free from restraint or seclu-

sion, of any form, imposed as a means of coercion, discipline, convenience, or retaliation by staff. Restraint or seclusion may only be imposed to ensure the immediate physical safety of the patient, a staff member, or others and must be discontinued at the earliest possible time.

(1) *Definitions.* (i) A *restraint* is—

(A) Any manual method, physical or mechanical device, material, or equipment that immobilizes or reduces the ability of a patient to move his or her arms, legs, body, or head freely; or

(B) A drug or medication when it is used as a restriction to manage the patient's behavior or restrict the patient's freedom of movement and is not a standard treatment or dosage for the patient's condition.

(C) A restraint does not include devices, such as orthopedically prescribed devices, surgical dressings or bandages, protective helmets, or other methods that involve the physical holding of a patient for the purpose of conducting routine physical examinations or tests, or to protect the patient from falling out of bed, or to permit the patient to participate in activities without the risk of physical harm (this does not include a physical escort).

(ii) *Seclusion* is the involuntary confinement of a patient alone in a room or area from which the patient is physically prevented from leaving. Seclusion may only be used for the management of violent or self-destructive behavior.

(2) Restraint or seclusion may only be used when less restrictive interventions have been determined to be ineffective to protect the patient a staff member or others from harm.

(3) The type or technique of restraint or seclusion used must be the least restrictive intervention that will be effective to protect the patient, a staff member, or others from harm.

(4) The use of restraint or seclusion must be—

(i) In accordance with a written modification to the patient's plan of care; and

(ii) Implemented in accordance with safe and appropriate restraint and seclusion techniques as determined by hospital policy in accordance with State law.

(5) The use of restraint or seclusion must be in accordance with the order of a physician or other licensed independent practitioner who is responsible for the care of the patient as specified under § 482.12(c) and authorized to order restraint or seclusion by hospital policy in accordance with State law.

(6) Orders for the use of restraint or seclusion must never be written as a standing order or on an as needed basis (PRN).

(7) The attending physician must be consulted as soon as possible if the attending physician did not order the restraint or seclusion.

(8) Unless superseded by State law that is more restrictive—

(i) Each order for restraint or seclusion used for the management of violent or self-destructive behavior that jeopardizes the immediate physical safety of the patient, a staff member, or others may only be renewed in accordance with the following limits for up to a total of 24 hours:

(A) 4 hours for adults 18 years of age or older;

(B) 2 hours for children and adolescents 9 to 17 years of age; or

(C) 1 hour for children under 9 years of age; and

(ii) After 24 hours, before writing a new order for the use of restraint or seclusion for the management of violent or self-destructive behavior, a physician or other licensed independent practitioner who is responsible for the care of the patient as specified under § 482.12(c) of this part and authorized to order restraint or seclusion by hospital policy in accordance with State law must see and assess the patient.

(iii) Each order for restraint used to ensure the physical safety of the non-violent or non-self-destructive patient may be renewed as authorized by hospital policy.

(9) Restraint or seclusion must be discontinued at the earliest possible time, regardless of the length of time identified in the order.

(10) The condition of the patient who is restrained or secluded must be monitored by a physician, other licensed independent practitioner or trained staff that have completed the training criteria specified in paragraph (f) of

this section at an interval determined by hospital policy.

(11) Physician and other licensed independent practitioner training requirements must be specified in hospital policy. At a minimum, physicians and other licensed independent practitioners authorized to order restraint or seclusion by hospital policy in accordance with State law must have a working knowledge of hospital policy regarding the use of restraint or seclusion.

(12) When restraint or seclusion is used for the management of violent or self-destructive behavior that jeopardizes the immediate physical safety of the patient, a staff member, or others, the patient must be seen face-to-face within 1 hour after the initiation of the intervention—

(i) By a—

(A) Physician or other licensed independent practitioner; or

(B) Registered nurse or physician assistant who has been trained in accordance with the requirements specified in paragraph (f) of this section.

(ii) To evaluate—

(A) The patient's immediate situation;

(B) The patient's reaction to the intervention;

(C) The patient's medical and behavioral condition; and

(D) The need to continue or terminate the restraint or seclusion.

(13) States are free to have requirements by statute or regulation that are more restrictive than those contained in paragraph (e)(12)(i) of this section.

(14) If the face-to-face evaluation specified in paragraph (e)(12) of this section is conducted by a trained registered nurse or physician assistant, the trained registered nurse or physician assistant must consult the attending physician or other licensed independent practitioner who is responsible for the care of the patient as specified under § 482.12(c) as soon as possible after the completion of the 1-hour face-to-face evaluation.

(15) All requirements specified under this paragraph are applicable to the simultaneous use of restraint and seclusion. Simultaneous restraint and seclusion use is only permitted if the patient is continually monitored—

(i) Face-to-face by an assigned, trained staff member; or

(ii) By trained staff using both video and audio equipment. This monitoring must be in close proximity to the patient.

(16) When restraint or seclusion is used, there must be documentation in the patient's medical record of the following:

(i) The 1-hour face-to-face medical and behavioral evaluation if restraint or seclusion is used to manage violent or self-destructive behavior;

(ii) A description of the patient's behavior and the intervention used;

(iii) Alternatives or other less restrictive interventions attempted (as applicable);

(iv) The patient's condition or symptom(s) that warranted the use of the restraint or seclusion; and

(v) The patient's response to the intervention(s) used, including the rationale for continued use of the intervention.

(f) *Standard: Restraint or seclusion: Staff training requirements.* The patient has the right to safe implementation of restraint or seclusion by trained staff.

(1) *Training intervals.* Staff must be trained and able to demonstrate competency in the application of restraints, implementation of seclusion, monitoring, assessment, and providing care for a patient in restraint or seclusion—

(i) Before performing any of the actions specified in this paragraph;

(ii) As part of orientation; and

(iii) Subsequently on a periodic basis consistent with hospital policy.

(2) *Training content.* The hospital must require appropriate staff to have education, training, and demonstrated knowledge based on the specific needs of the patient population in at least the following:

(i) Techniques to identify staff and patient behaviors, events, and environmental factors that may trigger circumstances that require the use of a restraint or seclusion.

(ii) The use of nonphysical intervention skills.

(iii) Choosing the least restrictive intervention based on an individualized assessment of the patient's medical, or behavioral status or condition.

(iv) The safe application and use of all types of restraint or seclusion used in the hospital, including training in how to recognize and respond to signs of physical and psychological distress (for example, positional asphyxia);

(v) Clinical identification of specific behavioral changes that indicate that restraint or seclusion is no longer necessary.

(vi) Monitoring the physical and psychological well-being of the patient who is restrained or secluded, including but not limited to, respiratory and circulatory status, skin integrity, vital signs, and any special requirements specified by hospital policy associated with the 1-hour face-to-face evaluation.

(vii) The use of first aid techniques and certification in the use of cardiopulmonary resuscitation, including required periodic recertification.

(3) *Trainer requirements.* Individuals providing staff training must be qualified as evidenced by education, training, and experience in techniques used to address patients' behaviors.

(4) *Training documentation.* The hospital must document in the staff personnel records that the training and demonstration of competency were successfully completed.

(g) *Standard: Death reporting requirements:* Hospitals must report deaths associated with the use of seclusion or restraint.

(1) With the exception of deaths described under paragraph (g)(2) of this section, the hospital must report the following information to CMS by telephone, facsimile, or electronically, as determined by CMS, no later than the close of business on the next business day following knowledge of the patient's death:

(i) Each death that occurs while a patient is in restraint or seclusion.

(ii) Each death that occurs within 24 hours after the patient has been removed from restraint or seclusion.

(iii) Each death known to the hospital that occurs within 1 week after restraint or seclusion where it is reasonable to assume that use of restraint or placement in seclusion contributed directly or indirectly to a patient's death, regardless of the type(s) of restraint used on the patient during this time. "Reasonable to assume" in this

context includes, but is not limited to, deaths related to restrictions of movement for prolonged periods of time, or death related to chest compression, restriction of breathing, or asphyxiation.

(2) When no seclusion has been used and when the only restraints used on the patient are those applied exclusively to the patient's wrist(s), and which are composed solely of soft, non-rigid, cloth-like materials, the hospital staff must record in an internal log or other system, the following information:

(i) Any death that occurs while a patient is in such restraints.

(ii) Any death that occurs within 24 hours after a patient has been removed from such restraints.

(3) The staff must document in the patient's medical record the date and time the death was:

(i) Reported to CMS for deaths described in paragraph (g)(1) of this section; or

(ii) Recorded in the internal log or other system for deaths described in paragraph (g)(2) of this section.

(4) For deaths described in paragraph (g)(2) of this section, entries into the internal log or other system must be documented as follows:

(i) Each entry must be made not later than seven days after the date of death of the patient.

(ii) Each entry must document the patient's name, date of birth, date of death, name of attending physician or other licensed independent practitioner who is responsible for the care of the patient as specified under § 482.12(c), medical record number, and primary diagnosis(es).

(iii) The information must be made available in either written or electronic form to CMS immediately upon request.

(h) *Standard: Patient visitation rights.* A hospital must have written policies and procedures regarding the visitation rights of patients, including those setting forth any clinically necessary or reasonable restriction or limitation that the hospital may need to place on such rights and the reasons for the clinical restriction or limitation. A hospital must meet the following requirements:

(1) Inform each patient (or support person, where appropriate) of his or her visitation rights, including any clinical restriction or limitation on such rights, when he or she is informed of his or her other rights under this section.

(2) Inform each patient (or support person, where appropriate) of the right, subject to his or her consent, to receive the visitors whom he or she designates, including, but not limited to, a spouse, a domestic partner (including a same-sex domestic partner), another family member, or a friend, and his or her right to withdraw or deny such consent at any time.

(3) Not restrict, limit, or otherwise deny visitation privileges on the basis of race, color, national origin, religion, sex, gender identity, sexual orientation, or disability.

(4) Ensure that all visitors enjoy full and equal visitation privileges consistent with patient preferences.

[71 FR 71426, Dec. 8, 2006, as amended at 75 FR 70844, Nov. 19, 2010; 77 FR 29074, May 16, 2012]

EFFECTIVE DATE NOTES: 1. At 84 FR 51817, Sept. 30, 2019, § 482.13 was amended by revising paragraphs (e)(5), (e)(8)(ii), (e)(10) and (11), (e)(12)(i), (e)(14), and (g)(4)(ii), effective Nov. 29, 2019. For the convenience of the user, the revised text is set forth as follows:

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\* \* \* \* \*

(e) \* \* \*

(5) The use of restraint or seclusion must be in accordance with the order of a physician or other licensed practitioner who is responsible for the care of the patient and authorized to order restraint or seclusion by hospital policy in accordance with State law.

\* \* \* \* \*

(8) \* \* \*

(ii) After 24 hours, before writing a new order for the use of restraint or seclusion for the management of violent or self-destructive behavior, a physician or other licensed practitioner who is responsible for the care of the patient and authorized to order restraint or seclusion by hospital policy in accordance with State law must see and assess the patient.

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(10) The condition of the patient who is restrained or secluded must be monitored by a physician, other licensed practitioner, or trained staff that have completed the training criteria specified in paragraph (f) of this section at an interval determined by hospital policy.

(11) Physician and other licensed practitioner training requirements must be specified in hospital policy. At a minimum, physicians and other licensed practitioners authorized to order restraint or seclusion by hospital policy in accordance with State law must have a working knowledge of hospital policy regarding the use of restraint or seclusion.

(12) \* \* \*

(i) By a—

(A) Physician or other licensed practitioner.

(B) Registered nurse who has been trained in accordance with the requirements specified in paragraph (f) of this section.

\* \* \* \* \*

(14) If the face-to-face evaluation specified in paragraph (e)(12) of this section is conducted by a trained registered nurse, the trained registered nurse must consult the attending physician or other licensed practitioner who is responsible for the care of the patient as soon as possible after the completion of the 1-hour face-to-face evaluation.

\* \* \* \* \*

(g) \* \* \*

(4) \* \* \*

(ii) Each entry must document the patient's name, date of birth, date of death, name of attending physician or other licensed practitioner who is responsible for the care of the patient, medical record number, and primary diagnosis(es).

\* \* \* \* \*

EFFECTIVE DATE NOTES: 2. At 84 FR 51882, Sept. 30, 2019, § 482.13 was further amended by revising paragraph (d)(2), effective Nov. 29, 2019. For the convenience of the user, the revised text is set forth as follows:

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\* \* \* \* \*

(d) \* \* \*

(2) The patient has the right to access their medical records, including current medical records, upon an oral or written request, in the form and format requested by the individual, if it is readily producible in such form and format (including in an electronic form or format when such medical

records are maintained electronically); or, if not, in a readable hard copy form or such other form and format as agreed to by the facility and the individual, and within a reasonable time frame. The hospital must not frustrate the legitimate efforts of individuals to gain access to their own medical records and must actively seek to meet these requests as quickly as its record keeping system permits.

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**§ 482.15 Condition of participation: Emergency preparedness.**

The hospital must comply with all applicable Federal, State, and local emergency preparedness requirements. The hospital must develop and maintain a comprehensive emergency preparedness program that meets the requirements of this section, utilizing an all-hazards approach. The emergency preparedness program must include, but not be limited to, the following elements:

(a) *Emergency plan.* The hospital must develop and maintain an emergency preparedness plan that must be reviewed, and updated at least annually. The plan must do the following:

(1) Be based on and include a documented, facility-based and community-based risk assessment, utilizing an all-hazards approach.

(2) Include strategies for addressing emergency events identified by the risk assessment.

(3) Address patient population, including, but not limited to, persons at-risk; the type of services the hospital has the ability to provide in an emergency; and continuity of operations, including delegations of authority and succession plans.

(4) Include a process for cooperation and collaboration with local, tribal, regional, State, and Federal emergency preparedness officials' efforts to maintain an integrated response during a disaster or emergency situation, including documentation of the hospital's efforts to contact such officials and, when applicable, its participation in collaborative and cooperative planning efforts.

(b) *Policies and procedures.* The hospital must develop and implement emergency preparedness policies and procedures, based on the emergency

plan set forth in paragraph (a) of this section, risk assessment at paragraph (a)(1) of this section, and the communication plan at paragraph (c) of this section. The policies and procedures must be reviewed and updated at least annually. At a minimum, the policies and procedures must address the following:

(1) The provision of subsistence needs for staff and patients, whether they evacuate or shelter in place, include, but are not limited to the following:

(i) Food, water, medical, and pharmaceutical supplies.

(ii) Alternate sources of energy to maintain the following:

(A) Temperatures to protect patient health and safety and for the safe and sanitary storage of provisions.

(B) Emergency lighting.

(C) Fire detection, extinguishing, and alarm systems.

(D) Sewage and waste disposal.

(2) A system to track the location of on-duty staff and sheltered patients in the hospital's care during an emergency. If on-duty staff and sheltered patients are relocated during the emergency, the hospital must document the specific name and location of the receiving facility or other location.

(3) Safe evacuation from the hospital, which includes consideration of care and treatment needs of evacuees; staff responsibilities; transportation; identification of evacuation location(s); and primary and alternate means of communication with external sources of assistance.

(4) A means to shelter in place for patients, staff, and volunteers who remain in the facility.

(5) A system of medical documentation that preserves patient information, protects confidentiality of patient information, and secures and maintains the availability of records.

(6) The use of volunteers in an emergency and other emergency staffing strategies, including the process and role for integration of State and Federally designated health care professionals to address surge needs during an emergency.

(7) The development of arrangements with other hospitals and other providers to receive patients in the event of limitations or cessation of oper-

ations to maintain the continuity of services to hospital patients.

(8) The role of the hospital under a waiver declared by the Secretary, in accordance with section 1135 of the Act, in the provision of care and treatment at an alternate care site identified by emergency management officials.

(c) *Communication plan.* The hospital must develop and maintain an emergency preparedness communication plan that complies with Federal, State, and local laws and must be reviewed and updated at least annually. The communication plan must include all of the following:

(1) Names and contact information for the following:

(i) Staff.

(ii) Entities providing services under arrangement.

(iii) Patients' physicians.

(iv) Other hospitals and CAHs

(v) Volunteers.

(2) Contact information for the following:

(i) Federal, State, tribal, regional, and local emergency preparedness staff.

(ii) Other sources of assistance.

(3) Primary and alternate means for communicating with the following:

(i) Hospital's staff.

(ii) Federal, State, tribal, regional, and local emergency management agencies.

(4) A method for sharing information and medical documentation for patients under the hospital's care, as necessary, with other health care providers to maintain the continuity of care.

(5) A means, in the event of an evacuation, to release patient information as permitted under 45 CFR 164.510(b)(1)(ii).

(6) A means of providing information about the general condition and location of patients under the facility's care as permitted under 45 CFR 164.510(b)(4).

(7) A means of providing information about the hospital's occupancy, needs, and its ability to provide assistance, to the authority having jurisdiction, the Incident Command Center, or designee.

(d) *Training and testing.* The hospital must develop and maintain an emergency preparedness training and testing program that is based on the emergency plan set forth in paragraph (a) of this section, risk assessment at paragraph (a)(1) of this section, policies and procedures at paragraph (b) of this section, and the communication plan at paragraph (c) of this section. The training and testing program must be reviewed and updated at least annually.

(1) *Training program.* The hospital must do all of the following:

(i) Initial training in emergency preparedness policies and procedures to all new and existing staff, individuals providing services under arrangement, and volunteers, consistent with their expected role.

(ii) Provide emergency preparedness training at least annually.

(iii) Maintain documentation of the training.

(iv) Demonstrate staff knowledge of emergency procedures.

(2) *Testing.* The hospital must conduct exercises to test the emergency plan at least annually. The hospital must do all of the following:

(i) Participate in a full-scale exercise that is community-based or when a community-based exercise is not accessible, an individual, facility-based. If the hospital experiences an actual natural or man-made emergency that requires activation of the emergency plan, the hospital is exempt from engaging in a community-based or individual, facility-based full-scale exercise for 1 year following the onset of the actual event.

(ii) Conduct an additional exercise that may include, but is not limited to the following:

(A) A second full-scale exercise that is community-based or individual, facility-based.

(B) A tabletop exercise that includes a group discussion led by a facilitator, using a narrated, clinically-relevant emergency scenario, and a set of problem statements, directed messages, or prepared questions designed to challenge an emergency plan.

(iii) Analyze the hospital's response to and maintain documentation of all drills, tabletop exercises, and emer-

gency events, and revise the hospital's emergency plan, as needed.

(e) *Emergency and standby power systems.* The hospital must implement emergency and standby power systems based on the emergency plan set forth in paragraph (a) of this section and in the policies and procedures plan set forth in paragraphs (b)(1)(i) and (ii) of this section.

(1) *Emergency generator location.* The generator must be located in accordance with the location requirements found in the Health Care Facilities Code (NFPA 99 and Tentative Interim Amendments TIA 12-2, TIA 12-3, TIA 12-4, TIA 12-5, and TIA 12-6), Life Safety Code (NFPA 101 and Tentative Interim Amendments TIA 12-1, TIA 12-2, TIA 12-3, and TIA 12-4), and NFPA 110, when a new structure is built or when an existing structure or building is renovated.

(2) *Emergency generator inspection and testing.* The hospital must implement the emergency power system inspection, testing, and maintenance requirements found in the Health Care Facilities Code, NFPA 110, and Life Safety Code.

(3) *Emergency generator fuel.* Hospitals that maintain an onsite fuel source to power emergency generators must have a plan for how it will keep emergency power systems operational during the emergency, unless it evacuates.

(f) *Integrated healthcare systems.* If a hospital is part of a healthcare system consisting of multiple separately certified healthcare facilities that elects to have a unified and integrated emergency preparedness program, the hospital may choose to participate in the healthcare system's coordinated emergency preparedness program. If elected, the unified and integrated emergency preparedness program must—

(1) Demonstrate that each separately certified facility within the system actively participated in the development of the unified and integrated emergency preparedness program.

(2) Be developed and maintained in a manner that takes into account each separately certified facility's unique circumstances, patient populations, and services offered.

(3) Demonstrate that each separately certified facility is capable of actively

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using the unified and integrated emergency preparedness program and is in compliance with the program.

(4) Include a unified and integrated emergency plan that meets the requirements of paragraphs (a)(2), (3), and (4) of this section. The unified and integrated emergency plan must also be based on and include the following:

(i) A documented community-based risk assessment, utilizing an all-hazards approach.

(ii) A documented individual facility-based risk assessment for each separately certified facility within the health system, utilizing an all-hazards approach.

(5) Include integrated policies and procedures that meet the requirements set forth in paragraph (b) of this section, a coordinated communication plan and training and testing programs that meet the requirements of paragraphs (c) and (d) of this section, respectively.

(g) *Transplant hospitals.* If a hospital has one or more transplant centers (as defined in § 482.70)—

(1) A representative from each transplant center must be included in the development and maintenance of the hospital's emergency preparedness program; and

(2) The hospital must develop and maintain mutually agreed upon protocols that address the duties and responsibilities of the hospital, each transplant center, and the OPO for the DSA where the hospital is situated, unless the hospital has been granted a waiver to work with another OPO, during an emergency.

(h) The standards incorporated by reference in this section are approved for incorporation by reference by the Director of the Office of the Federal Register in accordance with 5 U.S.C. 552(a) and 1 CFR part 51. You may obtain the material from the sources listed below. You may inspect a copy at the CMS Information Resource Center, 7500 Security Boulevard, Baltimore, MD or at the National Archives and Records Administration (NARA). For information on the availability of this material at NARA, call 202-741-6030, or go to: [http://www.archives.gov/federal\\_register/code\\_of\\_federal\\_regulations/](http://www.archives.gov/federal_register/code_of_federal_regulations/)

*ibr\_locations.html*. If any changes in this edition of the Code are incorporated by reference, CMS will publish a document in the FEDERAL REGISTER to announce the changes.

(1) National Fire Protection Association, 1 Batterymarch Park, Quincy, MA 02169, [www.nfpa.org](http://www.nfpa.org), 1.617.770.3000.

(i) NFPA 99, Health Care Facilities Code, 2012 edition, issued August 11, 2011.

(ii) Technical interim amendment (TIA) 12-2 to NFPA 99, issued August 11, 2011.

(iii) TIA 12-3 to NFPA 99, issued August 9, 2012.

(iv) TIA 12-4 to NFPA 99, issued March 7, 2013.

(v) TIA 12-5 to NFPA 99, issued August 1, 2013.

(vi) TIA 12-6 to NFPA 99, issued March 3, 2014.

(vii) NFPA 101, Life Safety Code, 2012 edition, issued August 11, 2011.

(viii) TIA 12-1 to NFPA 101, issued August 11, 2011.

(ix) TIA 12-2 to NFPA 101, issued October 30, 2012.

(x) TIA 12-3 to NFPA 101, issued October 22, 2013.

(xi) TIA 12-4 to NFPA 101, issued October 22, 2013.

(xii) NFPA 110, Standard for Emergency and Standby Power Systems, 2010 edition, including TIAs to chapter 7, issued August 6, 2009.

(2) [Reserved]

[81 FR 64028, Sept. 16, 2016; 81 FR 80594, Nov. 16, 2016]

EFFECTIVE DATE NOTE: At 84 FR 51817, Sept. 30, 2019, § 482.15 was amended by revising paragraphs (a) introductory text, (a)(4), (b) introductory text, (c) introductory text, (d) introductory text, and (d)(1)(ii); adding paragraph (d)(1)(v); revising paragraph (d)(2); in paragraph (g) introductory text, by removing the phrase “transplant centers” and adding into its place the phrase “transplant programs”; and in paragraphs (g)(1) and (2), by removing the phrase “transplant center” and adding into its place the phrase “transplant program”, effective Nov. 29, 2019. For the convenience of the user, the added and revised text is set forth as follows:

**§ 482.15 Condition of participation: Emergency preparedness.**

\* \* \* \* \*

## § 482.21

(a) *Emergency plan.* The hospital must develop and maintain an emergency preparedness plan that must be reviewed, and updated at least every 2 years. The plan must do the following:

\* \* \* \* \*

(4) Include a process for cooperation and collaboration with local, tribal, regional, State, and Federal emergency preparedness officials' efforts to maintain an integrated response during a disaster or emergency situation.

(b) *Policies and procedures.* The hospital must develop and implement emergency preparedness policies and procedures, based on the emergency plan set forth in paragraph (a) of this section, risk assessment at paragraph (a)(1) of this section, and the communication plan at paragraph (c) of this section. The policies and procedures must be reviewed and updated at least every 2 years. At a minimum, the policies and procedures must address the following:

\* \* \* \* \*

(c) *Communication plan.* The hospital must develop and maintain an emergency preparedness communication plan that complies with Federal, State, and local laws and must be reviewed and updated at least every 2 years. The communication plan must include all of the following:

\* \* \* \* \*

(d) *Training and testing.* The hospital must develop and maintain an emergency preparedness training and testing program that is based on the emergency plan set forth in paragraph (a) of this section, risk assessment at paragraph (a)(1) of this section, policies and procedures at paragraph (b) of this section, and the communication plan at paragraph (c) of this section. The training and testing program must be reviewed and updated at least every 2 years.

(1) \* \* \*

(ii) Provide emergency preparedness training at least every 2 years.

\* \* \* \* \*

(v) If the emergency preparedness policies and procedures are significantly updated, the hospital must conduct training on the updated policies and procedures.

(2) *Testing.* The hospital must conduct exercises to test the emergency plan at least twice per year. The hospital must do all of the following:

(i) Participate in an annual full-scale exercise that is community-based; or

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(A) When a community-based exercise is not accessible, conduct an annual individual, facility-based functional exercise; or.

(B) If the hospital experiences an actual natural or man-made emergency that requires activation of the emergency plan, the hospital is exempt from engaging in its next required full-scale community-based exercise or individual, facility-based functional exercise following the onset of the emergency event.

(ii) Conduct an additional annual exercise that may include, but is not limited to the following:

(A) A second full-scale exercise that is community-based or an individual, facility-based functional exercise; or

(B) A mock disaster drill; or

(C) A tabletop exercise or workshop that is led by a facilitator and includes a group discussion, using a narrated, clinically-relevant emergency scenario, and a set of problem statements, directed messages, or prepared questions designed to challenge an emergency plan.

(iii) Analyze the hospital's response to and maintain documentation of all drills, tabletop exercises, and emergency events, and revise the hospital's emergency plan, as needed.

\* \* \* \* \*

## Subpart C—Basic Hospital Functions

### § 482.21 Condition of participation: Quality assessment and performance improvement program.

The hospital must develop, implement, and maintain an effective, ongoing, hospital-wide, data-driven quality assessment and performance improvement program. The hospital's governing body must ensure that the program reflects the complexity of the hospital's organization and services; involves all hospital departments and services (including those services furnished under contract or arrangement); and focuses on indicators related to improved health outcomes and the prevention and reduction of medical errors. The hospital must maintain and demonstrate evidence of its QAPI program for review by CMS.

(a) *Standard: Program scope.* (1) The program must include, but not be limited to, an ongoing program that shows measurable improvement in indicators for which there is evidence that it will